

Atty. Docket: 1135-21 RE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Vladimir A. Stoy
Gerald Gontarz **EXAMINER:** Alvin J. Stewart

SERIAL NO.: 10/625,390 **ART UNIT:** 3738

FILED: July 23, 2003

FOR: Spinal Nucleus Implant

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF VLADIMIR A. STOY UNDER 37 CFR § 1.131

Sir:

I, Vladimir A. Stoy, do aver that I, along with Gerald Gontarz, conceived the claimed subject matter in the above-identified patent application in the U.S. prior to the filing date of United States Patent Application Publication Number 2002/0183848 to Ray et al. ("Ray").

The Ray application was filed on July 24, 2002 and was published on December 5, 2002. The Ray application is a continuation of application No. 09/286,047, filed on April 5, 1999, according to the bibliographic information on the face of the published Ray application. However, I, along with Mr. Gontarz, conceived the claimed subject matter before April 5, 1999. In support thereof, I am attaching copies of sheets from the laboratory notebook of Gerald Gontarz with notebook entries. These sheets from Mr. Gontarz's laboratory notebook clearly show and support the claimed subject matter in the

instant application. The notebook pages reflect subject matter that I, along with Mr. Gontarz, conceived of prior to April 5, 1999.

The sheets labeled "A" and "B" of Mr. Gontarz laboratory notebook clearly show conception of a spinal nucleus implant that has shape memory from an Aquacryl polymer, i.e., a swellable, biomimetic plastic, having a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, the biomimetic plastic having an inherent shape in which it has a relaxed polymer network in a state of full hydration, having an insertion shape in which it is at least partially dehydrated to a xerogel state and formable into a compacted mode for maximum efficiency of surgical insertion, and capable of anisotropic expansion due to partial rehydration in situ into an indwelling shape that substantially conforms to the size and shape of said cavity and is capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state, the anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes. The notes and tables which are depicted and memorialized in Mr. Gontarz's laboratory notebook clearly support the claimed subject matter of the instant application.

References to Li Medical in the attached notebook pages relate to a company that was considered for manufacture of instruments for insertion of the spinal nucleus implant. Any disclosure of the implant to Li Medical personnel was made under confidentiality pursuant to a collaboration agreement and was not made for purposes of selling spinal nucleus implants.

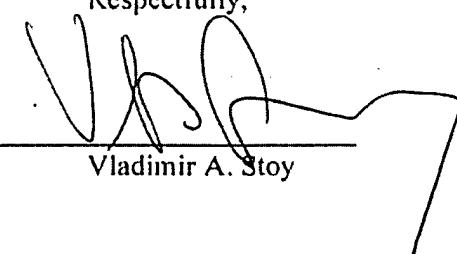
Further still, these sheets from Mr. Gontarz's laboratory notebook reflect subject

matter that I and Mr. Gontarz conceived of before April 5, 1999 and clearly demonstrate a conception and reduction to practice before the filing date of Ray. See, for example, the "spinal nucleus swelling in salt solution" measurements on the page labeled "A", the reference to "aquacryl" and "spinal nucleus that has a shape memory" on the page labeled "B", and the specific indication on the page labeled "B" that the samples were saved. As can be seen from the specification of the present application, e.g., Example 1, Aquacryl was used as a hydrogel in accordance with the invention. Therefore, Ray is not prior art to the instant application and cannot be applied against the claimed subject matter.

I am aware that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. All statements herein made of my own knowledge are true and all statements herein made on information and belief are believed to be true.

March 6, 2005

Dated

Respectfully,

Vladimir A. Stoy

A

95

Optical Nucleus Dwell Time in milli seconds

| SAMPLE | TIME |
|-----------|--------|
| 26.9.77-A | 4.0000 |
| B | 3.5426 |
| 26.2.74-A | 4.4303 |
| B | 4.4413 |
| C | 4.3346 |
| D | 3.9611 |
| E | 3.2109 |
| F | 2.8986 |

B

10614

1000

113

~~to make dried blocks~~

and make "readable" type aquacryl in
to make a spinal nucleus that has a shape memory.
8% w/v aquacryl as a base will cross link 50%
water, then add in saline. There will be plasticized
will be held then crosslinked as follows:

| COMPOSITION: | | COMPOSITION: | | COMPOSITION: | |
|------------------------|---------------------|---------------------|---------------|---------------|---------------|
| Initial water content: | NaCl concentration: | NaCl concentration: | Water weight: | Water weight: | Water weight: |
| | 0.0% | 0.0% | | | |
| Weight | Polymer wt | w2 | NaBGN | Water | |
| Initial state: | 342.80 | 37.80 | 0.1100 | weight | |
| Swollen state: | 263.81 | 37.80 | 0.1429 | 22.6124 | 241.0547 |
| | Liquid wt. | Target wt. | Poly conc: | | |
| Target concentration: | 45.0% | 362.24978 | 67.94 | 42.8% | 71.2 |
| | 50.0% | 49.2248 | 82.91 | 45.5% | |
| Target: | 55.0% | 41.11343 | 78.80 | 47.8% | |
| | 60.0% | 37.88733 | 75.57 | 50.0% | |
| Will evaporate | | 175.87 | g of water | | |
| By evap: | | 645.40000 | g of water | | |

will edge there into circles and heat to 100°C for
15 minutes in order to incite a shape. This will be
washed and plasticized as normal procedures.

Dangler saved at 36-9-107-A